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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,393	01/28/2002	Linda J. Richardson Casella		7390

7590

05/01/2003

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EXAMINER

SAUCIER, SANDRA E

ART UNIT PAPER NUMBER

1651

DATE MAILED: 05/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/058,393

Applicant(s)
Richardson-Casella et al.

Examiner
Sandra Saucier

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 18, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) 1-6 and 11-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-18 are pending. Claims 7-10 are considered on the merits. Claims 1-6, 11-18 are withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

Claims 1-6, 11-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse in Paper No. 3.

Claim Rejections – 35 USC § 112

INDEFINITE

Claims 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 7 states that a substance that confirms the presence of *E. coli* is a component of the medium; however, neither component c) nor d) are *E. coli* specific. The preamble and the components of the medium are in conflict.

In the interest of compact prosecution, one indicator is considered to be *E. coli* specific and the other is considered to be a general coliform indicator.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Manafi *et al.* [U].

The claims are directed to a medium for detecting coliforms and confirming the presence of *E. coli* comprising:

a) an antibiotic-free growth medium,

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- b) buffer to maintain at least pH 6,
- c) coliform sensitive chromogen,
- d) coliform sensitive fluorogen.

The references are relied upon as explained below.

Manafi *et al.* disclose various media for detecting coliforms and confirming the presence of *E. coli* comprising for example:

- a) an antibiotic-free growth medium (ECD-agar or laurylsulfate broth)
- b) buffers in the growth medium are phosphate based buffers (see page 228) in a proportion to maintain a pH of at least 6,
- c) coliform sensitive chromogen (5-bromo-4-chloro-3-indolyl- β -D-galactopyranoside for coliforms),
- d) coliform sensitive fluorogen (4-methylumbelliferyl- β -D-glucuronide for *E. coli*) (Fig. 1 and Table 2).

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,387,650 [A].

The claims are directed to a medium for detecting coliforms and confirming the presence of *E. coli* comprising:

- a) an antibiotic-free growth medium,
- b) buffer to maintain at least pH 6,
- c) coliform sensitive chromogen,

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d) coliform sensitive fluorogen.

The references are relied upon as explained below.

US 6,387,650 discloses a medium useful in testing food and water for bacterial contamination. It discloses in column 8, lines 4-10 that two substrates producing different types of detectable signals have been used to detect the presence of *E. coli* and total coliforms. *E. coli* produces a specific β -glucuronidase, while coliforms in general produce galactosidase. Thus, hydrolysis of 4-methylumbelliferyl- β -D-glucuronide produces a fluorophore specific for *E. coli*, while hydrolysis of orthonitrophenyl- β -D-galactopyranoside produces a chromophore indicative of coliform presence.

The medium used as a base for the chromogen/fluorogen is given in Tables II and III. The medium is an antibiotic-free growth medium, Table III, to which HEPES and the selected chromogen/fluorogen is added in Table II.

Although the pH of the mixture is not specifically given, it is assumed, in the absence of evidence to the contrary that 4.29 gm/l HEPES acid and 8.38 gms/l HEPES Na⁺ salt will produce a pH of at least 6.

In col. 2, l. 31, the medium is defined as being a powder or liquid. In Table II, peptone is added to the medium, which would increase the viscosity of the medium.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Manafi *et al.* [U] as applied to claims 7-9 above, and further in view of US 6,387,650 [A].

The claims are further directed to a powdered form of the media.

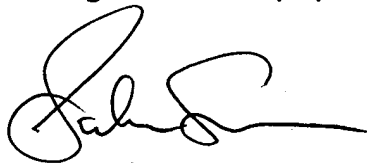
The production of the media of Manafi *et al.* in powdered form would have been obvious when taken with US 6,387,650 which teaches that media for the detection of coliforms/*E. coli* may either be in liquid or powdered form. Whether a medium is hydrated or dried is considered to be well within the purview of one of ordinary skill in the art, especially because these types of media are commonly sold as powders for convenience in shipping and because they are well known in the art.

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One of ordinary skill in the art would have been motivated at the time of invention to make this modification in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier
Primary Examiner
Art Unit 1651
April 30, 2003